IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement Therapy Products Liability Litigation	)	**Case No. 14 C 1748**
	)	**MDL No. 2545**
(This document applies to *Reynolds v. AbbVie Inc.*, Case No. 17 C 4117)	)	

CASE MANAGEMENT ORDER NO. 191
(Order on AbbVie's motion for summary judgment in *Reynolds v. AbbVie Inc.*, No. 17 C 4117)

MATTHEW F. KENNELLY, District Judge:

Plaintiffs in this multidistrict litigation (MDL) proceeding allege that they suffered either arterial cardiovascular injuries or injuries related to blood clots in the veins (venous thromboembolisms) as a result of taking prescription testosterone replacement therapy (TRT) drugs. Defendants AbbVie Inc., AbbVie Products LLC, Abbott Laboratories, Inc., and Unimed Pharmaceuticals, Inc (collectively, AbbVie) manufacture AndroGel, one of the TRT products at issue in this litigation. Tony Reynolds alleges that his use of AndroGel caused him to suffer a stroke in January 2014. He asserts claims against AbbVie for strict liability, negligence, redhibition, unjust enrichment, consumer protection, and breach of warranty, as well as other claims.

AbbVie has moved for summary judgment on all of Reynolds's claims. For the following reasons, the Court grants AbbVie's motion for summary judgment on the redhibition, unjust enrichment, and consumer protection claims but otherwise denies the motion.

Background

The Court assumes familiarity with the background as set out in its prior case management orders and therefore discusses only those details uniquely relevant to Reynolds's claims. The Court recounts the following facts from the parties' Local Rule 56.1 statements, exhibits, and summary judgment briefing. The facts are undisputed except where otherwise stated.

Reynolds is a citizen of Tennessee. On January 15, 2014, he began using AndroGel after his doctor prescribed it to treat fatigue and low libido. Six days later, on January 21, he was flown to a hospital after suffering a stroke. His treating physicians did not explain what caused his stroke, and Reynolds did not ask them about the possible causes. His medical records indicate that he received AndroGel while in rehabilitation, and upon being discharged on February 13, he was instructed to "take his medications as prescribed"—which included "AndroGel as per home dosing." Pl.'s LR 56.1 Stat., Ex. C at 2, 4.

During his deposition, Reynolds testified that he stopped using AndroGel shortly before he ran out of his prescription, which he believed was around February 5, 2014. He stated that he initially stopped taking all of his medications after his stroke but later resumed using most of them—especially insulin and other medications that he had been taking for years. AndroGel was one of several medications that Reynolds stated he "quit taking and [] didn't start back" after his stroke. Defs.' LR 56.1 Stat., Ex 4, Reynolds Dep. Tr. ("Reynolds Dep.") at 30:12–13. Reynolds never refilled his AndroGel prescription. He explained that he stopped all of his medications because he did not know how any of them had affected him, and the medications were "the only thing that

[he] could think of that would cause it." *Id.* at 33:18–19. When asked if he believed in 2014 that AndroGel in particular caused his stroke, Reynolds responded, "[n]ot really, no" and that he "was questioning all [his] medicine, everything [he] was taking." *Id.* at 31:9-11. Other than stopping some of his medications, Reynolds did not take further action to determine the cause of his stroke.

Reynolds testified that he first believed AndroGel may have caused his stroke a couple years later, after he saw television commercials about "having a suit against AndroGel and about different things it was causing." *Id.* at 42:14–16. He stated that he realized the symptoms described in the commercials were the same symptoms he had experienced, which led him to question if AndroGel could have caused his 2014 stroke. Reynolds contacted his counsel within months of seeing the commercial and filed this suit in April 2017 in the Eastern District of Tennessee.

Discussion

In multidistrict litigation, procedural matters are governed by the law of the transferee court. *See, e.g.*, *In re Pradaxa (Dabigatran Etexilate Prods. Liab. Litig.)*, No. 3:12-md-02385-DRH-SCW, 2013 WL 656822, at *2 (S.D. Ill. Feb 22, 2013); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 889 F. Supp. 2d 931, 936 n.7 (E.D. Ky. 2012); *Various Plaintiffs v. Various Defendants (Oil Field Cases)*, 673 F. Supp. 2d 358, 362 (E.D. Pa. 2009). A party is entitled to summary judgment if it shows that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). There is a genuine issue of material fact, and summary judgment is precluded, "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248

(1986). In ruling on a motion for summary judgment, a court examines the record in the light most favorable to the non-moving party and draws all reasonable inferences in that party's favor. *Id.* at 255; *see also Parker v. Four Seasons Hotels, Ltd.*, 845 F.3d 807, 812 (7th Cir. 2017).

"Summary judgment is properly granted on the basis of a statute of limitations defense if '(1) the statute of limitations has run, thereby barring the plaintiff's claim as a matter of law, and (2) there exist no genuine issues of material fact regarding the time at which plaintiff's claim has accrued and the application of the statute to plaintiff's claim which may be resolved in plaintiff's favor.'" *Massey v. United States*, 312 F.3d 272, 276 (7th Cir. 2002) (quoting *Green v. United States*, 765 F.2d 105, 107 (7th Cir. 1985)). "[T]he point at which a cause of action accrues may be determined as a matter of law if the relevant facts are undisputed and they lead to but one conclusion[,]" but "[i]f the accrual determination turns on the resolution of factual questions, however, summary judgment is inappropriate, and the statute of limitations issue must be submitted to a jury after trial." *Horn v. A.O. Smith Corp.*, 50 F.3d 1365, 1370 (7th Cir. 1995).

A. Statute of limitations

Under CMO 12, Reynolds's case "shall be treated as if originally filed in the federal district where [he] was a citizen at the time of the filing of his . . . first Complaint." CMO 12 § II.B.ii. For Reynolds, that district is the Eastern District of Tennessee—and therefore Tennessee's statute of limitations applies to this claim. *See Looper v. Cook Inc.*, 20 F.4th 387, 389 (7th Cir. 2021) (statute of limitations of plaintiffs' home states apply where plaintiffs filed their suit directly in the MDL pursuant to the district court's case management order). Tennessee law requires personal injury claims to be

"commenced within one (1) year after the cause of action accrued[,]" and in product liability cases "the cause of action for injury to the person shall accrue on the date of the personal injury, not the date of the negligence or the sale of a product[.]" Tenn. Code Ann. §§ 28-3-104(a)(1), (b)(2); *see also Sharp v. Richardson*, 937 S.W.2d 846, 847 (Tenn. 1996) (noting the "one-year products liability statute of limitations").

The Tennessee Supreme Court has also held, however, that the "discovery rule" is "applicable in tort actions, including but not restricted to products liability actions predicated on negligence, strict liability or misrepresentation[.]" *Potts v. Celotex Corp.*, 796 S.W.2d 678, 680 (Tenn. 1990). Under this rule, "the statute of limitations begins to run when the plaintiff knows or in the exercise of reasonable care and diligence should know that an injury has been sustained as a result of wrongful or tortious conduct by the defendant." *Shadrick v. Coker*, 963 S.W.2d 726, 733 (Tenn. 1998). The plaintiff must have "knowledge of facts sufficient to put [him] on notice that an injury has been sustained." *Id.* at 734 (internal citations and quotation marks omitted). "Such knowledge includes not only an awareness of the injury, but also the tortious origin or wrongful nature of that injury." *Id.*

Reynolds suffered his stroke in January 2014 and filed this suit in April 2017, so his claims would be time-barred if the statute of limitations began running immediately upon his stroke. Reynolds brought his claim within months of seeing commercials about the risks of AndroGel, however, and thus his suit would be timely if the discovery rule tolled the statute of limitations until he saw those commercials. AbbVie argues that because Reynolds stopped taking AndroGel after his prescription ran out and never refilled that prescription, he had sufficient knowledge of the injury to trigger the statute of

limitations immediately after his stroke. It also contends that the timing of Reynolds's stroke—six days after he began taking AndroGel—and parts of his deposition testimony support that conclusion, citing to his testimony that he "thought that one of [his medicines] might have caused [his] stroke" and that his medications were "the only thing that [he] could think of that would cause it." Mem. in Supp. of Def. AbbVie's Mot. for Summ. J. at 2 (quoting Reynolds Dep. at 32:2–4, 33:18–19).

Yet Tennessee law requires "not only an awareness of the injury, but also the *tortious origin or wrongful nature* of that injury." *Shadrick*, 963 S.W.2d at 734 (emphasis added). None of Reynolds's statements show that he knew or should have known immediately after his stroke that his "injury [was] sustained *as a result of wrongful or tortious conduct by the defendant*." *Id.* (emphasis added). Rather, Reynolds stated that he "wasn't sure if anything [he] had taken had caused anything, so [he] quit it all" and that "[t]here were several [medications] that [he] quit taking and [he] didn't start back." Reynolds Dep. at 30:5–6, 12–13. At multiple points in his deposition, Reynolds testified that he first had reason to suspect AndroGel in particular—rather than his medications generally—years after his stroke, when he saw a television commercial about its cardiovascular risks. His medical records also support this claim, as Reynolds continued to receive AndroGel while he was in rehabilitation, and his doctors instructed him to take all medications as prescribed—including "AndroGel as per home dosing"—despite knowing that he had recently suffered a stroke. Pl.'s LR 56.1 Stat., Ex. C at 2.

In contrast, AbbVie asks the Court to infer that Reynolds should have known that his injury was due to AbbVie's allegedly wrongful conduct because he started AndroGel, suffered a stroke six days later, and then stopped taking AndroGel after his stroke. At

this stage, however, the Court must draw all reasonable inferences in favor of Reynolds, the non-moving party. Consequently, the Court cannot conclude that Reynolds should have known of "wrongful or tortious conduct by" AbbVie when the same medical professionals who treated his stroke also instructed him to continue taking AndroGel. *Shadrick*, 963 S.W.2d at 734. Because a reasonable jury could find that Reynolds neither knew nor should have known of the alleged "tortious origin or wrongful nature" of AndroGel until he saw plaintiffs' counsel's television commercial, *id.*, there is a genuine factual dispute regarding whether the discovery rule tolls the statute of limitations. The Court therefore denies AbbVie's motion for summary judgment on this point.

B. Design defect

AbbVie contends that Reynolds's design defect claims are preempted, relying on *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d 281 (6th Cir. 2015), and a prior decision by this Court in this MDL. *See In re Testosterone Replacement Therapy*, No. 14 C 1748, MDL No. 2545, 2017 WL 1836435 (N.D Ill. May 8, 2017) ("*TRT I*"). Although the Court analyzed *Yates* in granting summary judgment on the bellwether plaintiffs' negligent design defect claims, in that same decision the Court also denied summary judgment on their strict liability design defect claims. *TRT I*, 2017 WL 1836435, at *19–20. In doing so, the Court held that Tennessee was one of several states that "appear to have adopted comment (k) to section 402(A) of the Restatement (Second) of Torts, which states that manufacturers of products that are 'unavoidably unsafe,' such as prescription medications, are 'not to be held to strict liability for unfortunate consequences attending their use'" if those medications were "properly prepared and marketed, *and proper warning is given*." *Id.* at *19 (internal citations and

quotation marks omitted) (emphasis in original); *see also Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428–29 (Tenn. 1994) ("Manufacturers of prescription drugs . . . have a duty to market and distribute their products in a way that minimizes the risk or danger. They may discharge their duty by distributing the drugs with proper directions and adequate warnings to those who foreseeably could be injured by the use of their products." (citing Restatement (Second) of Torts, § 402A comment k (1965))). The Court has previously found that "a genuine dispute exists regarding whether [AbbVie] provided adequate warnings," *TRT I*, 2017 WL 1836435, at *19, and AbbVie has presented no basis to conclude otherwise in this case. For this reason, the Court denies AbbVie's motion for summary judgment on Reynolds's strict liability design defect claim.

Reynolds argues that the Court's rationale for granting judgment on the bellwether plaintiffs' negligent design defect claim does not apply to his case. The Court previously granted summary judgment because it concluded that *Yates* foreclosed any design defect claims based on alternative product designs and the bellwether plaintiffs "cite[d] no case law which supports their contention that they can bring a negligent design defect claim without demonstrating the existence of a feasible alternative design." *TRT I*, 2017 WL 1836435, at *20. In contrast, Reynolds points to the "prudent manufacturer" test—which the bellwether plaintiffs did not raise at summary judgment—to argue that his negligent design defect claim does not require him to prove a feasible alternative design. Pl.'s Opp. to Summ. J. at 13 (citing *Brown v. Raymond Corp.*, 432 F.3d 640, 643–44 (6th Cir. 2005)).

Tennessee courts apply the prudent manufacturer test to determine whether a product is unreasonably dangerous. *Brown v. Crown Equip. Corp.*, 181 S.W.3d 268,

282 (Tenn. 2005). The Sixth Circuit has held that this test involves a risk-utility analysis that "effectively require[s] *either* a redesign of the product *or a stronger warning* to avoid liability for a design defect[.]" *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 397 (6th Cir. 2013) (emphasis added). Although *Strayhorn* stated that Tennessee design defect claims against generic drug manufacturers were preempted because "neither [a product redesign nor a stronger warning were] available to a *generic manufacturer* under federal law," *id.* (emphasis added), this Court and other courts have recognized that manufacturers may strengthen a *brand name* drug's warning label. *See, e.g.*, *In re Testosterone Replacement Therapy*, 430 F. Supp. 3d 516, 527 (N.D. Ill. 2019) ("But the FDA's 'changes being effected' (CBE) regulation . . . . for example, allows a manufacturer to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' without waiting for the FDA to approve the change.") (internal citations omitted) ("*TRT II*"); *Paulsen v. Abbott Labs.*, 368 F. Supp. 3d 1152, 1173 (N.D. Ill. 2019) ("FDA regulations allow drug manufactures some leeway to make changes unilaterally to the warning labels of brand name drugs like the ones at issue").

AbbVie contends that the prudent manufacturer test is equivalent to the "stop-selling" theory that the Supreme Court held was preempted. That argument is unavailing, however, because the prudent manufacturer test would not require AbbVie to stop selling AndroGel if it included a "stronger warning to avoid liability for design defect." *Strayhorn*, 737 F.3d at 397. AbbVie does not explain how it would have been impossible for it to include an appropriate warning under the prudent manufacturer test in light of the FDA's CBE regulation and this Court's decision in *TRT II*, and another court to have considered this issue post-*Yates* has noted that "[i]t remains unclear from

the Sixth Circuit's reasoning why the design defect claim could not have survived in light of the risk-utility factor of strengthening a warning label, which may or may not be preempted." *Brazil v. Janssen Research & Dev. LLC*, 249 F. Supp. 3d 1321, 1347 (N.D. Ga. 2016). Because this Court also reads *Yates* as limited to design defect claims based on alternative designs, it concludes that neither Reynolds's strict liability nor negligent design defect claims are preempted and denies AbbVie's motion for summary judgment on this point. [1] [2]

D. Breach of warranty

Reynolds contends that a four-year statute of limitations applies to his breach of warranty claim, citing to *Commercial Truck & Trailer Sales, Inc. v. McCampbell*, 580 S.W.2d 765, 773 (Tenn. 1979). Since *McCampbell*, however, the Tennessee Supreme Court has held that the one-year statute of limitations applies to various claims seeking to recover for "injuries to the person" because "[i]t is well settled in this state that the gravamen of an action, rather than its designation as an action for tort or contract, determines the applicable statute of limitations." *Pera v. Kroger Co.*, 674 S.W.2d 715, 719 (Tenn. 1984). To determine the gravamen of an action, courts look to "the basis of

[1] AbbVie cites to *Fleming v. Janssen Pharmaceuticals, Inc.*, 186 F. Supp. 3d 826, 833–34 (W.D. Tenn. 2016), which applies *Yates* in finding that strict liability and negligent design defect claims are preempted. But *Fleming* says only that "*Yates* is controlling authority in the instant case," *id.* at 834, and it does not address comment (k) or the prudent manufacturer test. Because the Court believes *Yates* does not reach comment (k) or warning-based design defect claims, it declines to adopt *Fleming*'s position.

[2] AbbVie also argues that Tennessee does not recognize design defect claims based on a defective warning. That is not the law. *See Flax v. DaimlerChrysler Corp.*, 272 S.W.3d 521, 541 (Tenn. 2008) ("Tennessee courts have long held that a manufacturer may be held strictly liable for failing to warn consumers of the dangers of a particular product at the time of sale.").

the legal claim and the type of injury sustained." *Benz-Elliott v. Barrett Enters., LP*, 456 S.W.3d 140, 151 (Tenn. 2015); *see also Pera*, 674 S.W.2d at 720–21 (although the plaintiff insisted her action was "based on a contract," one-year statute of limitations for personal injury claims applied because she sought to recover damages for "mental anguish, humiliation, embarrassment, and damage to reputation"). Reynolds primarily seeks to recover damages for past and future medical bills, pain and suffering, emotional distress, and lost opportunity and income. Despite claiming these "injuries to the person," *Pera*, 674 S.W.2d at 719, Reynolds cites to no case law in light of *Pera* and *Benz-Elliott* that apply a four-year statute of limitations for claims involving such damages. The Court therefore concludes that the one-year statute of limitations period also applies to Reynolds's breach of warranty claim. Yet because there is a genuine factual dispute regarding whether the discovery rule tolls the statute of limitations, *see* Section A, *supra*, a reasonable jury could find that Reynolds's breach of warranty claim is timely even if the limitations period is one year.

The parties also dispute whether Tennessee law requires Reynolds to provide AbbVie with notice of its alleged breach before he filed his suit. Neither side cites to any controlling authority, but Reynolds notes that *Smith v. Pfizer Inc.*, 688 F. Supp. 2d 735 (W.D. Tenn. 2010), analyzed this exact question and held that there was no pre-suit notice requirement. The court in *Smith* noted that "[n]othing in the plain text of the statute indicates that a lawsuit cannot serve as [the] notification[,]" other jurisdictions are split on the question, and "[i]t does not appear that Tennessee courts have squarely addressed this issue." *Id.* at 750. The court then pointed out that "notice serves a different purpose in personal injury cases" and concluded that those "purposes are

served just as well by the filing of a lawsuit as by a separate, pre-suit notification." *Id.* at 751. The Court finds *Smith* persuasive given its in-depth analysis of the statute's purpose, and therefore it denies AbbVie's motion for summary judgment on Reynolds's breach of warranty claim.

E. Other Claims

Reynolds states that he will not pursue his redhibition, unjust enrichment, or consumer protection claims. Consequently, the Court grants AbbVie's motion for summary judgment on those claims.

Conclusion

For the foregoing reasons, the Court grants AbbVie's motion for summary judgment [dkt. no. 32] on Reynolds's redhibition, unjust enrichment, and consumer protection claims. It denies the motion on all of Reynolds's other claims, including his strict liability, negligence, and breach of warranty claims.

MATTHEW F. KENNELLY
United States District Judge

Date: February 7, 2023